ECA ACADEMY

With Pre-Conference Workshop on "Microbiological Deviations (OOS/OOL)" on 5 May 2015

European Microbiology Conference

6-7 May 2015, Prague, Czech Republic

HIGHLIGHTS

Workshop

Deviation Handling for

- Non Sterile Products
- Sterile Products
- Biopharmaceuticals
- Endotoxins

European Microbiology Conference

- Regulatory Updates
- Microbiological Methods and their Validation
- Contamination Control
- Experiences from Cognate Industries

SPEAKERS

DR JESSICA COLE
FDA/CDER Office of Pharmaceutical Quality's Division of Microbiology Assessment

DR STEFANIE BAYER
Labor L+S AG

DR JÖRG DEGEN
Bioservice Laboratories

DR SVEN M. DEUTSCHMANN
Roche Diagnostics

DR WOLFGANG EDER
Roche Diagnostics

DR ANJA FRIEDRICH
BSL

BARBARA GERTEN
Merck Millipore

LAURA GUARDI
Ecolab

DR ANNETT KILIC
Greiner Bio-One

NEIL LEWIS
Procter & Gamble

DR PAUL LUKES
GlaxoSmithKline

ESTHER MARTY
Novartis

CARSTEN MOSCHNER
Dastex

DR ROCCO PETRIZZO
TSI

JIM POLARINE
Steris

DR GUY ROEHRIG
Lilly

DR DAVID ROESTI
Novartis

DR ANNA SCHERZINGER
Hyglos

DR FREIMUT WILBORN
Berlin Chemie

This conferences is recognised for the ECA GMP Certification Programme „Certified Microbological Laboratory Manager". Please find details at www.gmp-certification.eu

Invitation to the European Microbiology Conference 2015 with pre-conference workshop on "Microbiological Deviations"

Dear Colleague,

I would like to invite you to the European Microbiology Conference (EMC) and the Microbiological Deviation Workshop 2015 organised by the ECA Academy.

Referring to the very good responses from attendants, speakers and exhibitors after the first EMC in 2008, it became an annual event with presentations and workshops on current topics in pharmaceutical microbiology. In 2015, the EMC will be combined with a Pre-Conference Workshop on the handling of microbiological Out-of Specification (OOS) and Out-of-limit (OOL) results.

Contrary to deviations in chemical analytics, there still exists no really suitable guideline for dealing with deviations in the field of microbiology. Due to this fact we want to address this topic in a special workshop session to look at it from various angles and to provide you with information about the regulatory background as well as with practical examples and strategies for handling OOS/OOL results. Pharmacopoeial experts, representatives from pharmaceutical quality control and from testing laboratories will show you what are the challenges of the bioburden control strategy and how they implemented an adequate control in their companies.

The pharmaceutical microbiologist plays a key role in all aspects of development, manufacture and control of medicinal products, and their components. It is thus the aim of this conference and workshop to equip the pharmaceutical microbiologist with practical and applicable knowledge and "know how". In addition it will provide a forum for interesting and open discussions between presenters, regulators and your colleagues from the industry.

It would be a great pleasure for me if you joined us in Prague.

Dr Sven M Deutschmann
Chairman of ECA's RMM Working Group

Pre-Conference Workshop "Microbiological Deviations"

5 May 2015, Prague, Czech Republic

Objectives

This Workshop will show you the regulatory background as well as provide you with practical guidance for a scientific and systematic way to handle microbiological deviations. Experienced Experts will give you guidance on how to handle them in the different fields of microbiological QC like

- Pharmaceutical Water
- Environmental Monitoring
- Objectionable Microorganisms
- Sterility Testing
- Endotoxin testing
- Biological/biopharmaceutical manufacturing

Background

Until today the non-compliant handling of OOS is one of the most common deviations in FDA's "483s" and Warning Letters, despite the different guidelines and recommendations for the handling of OOS results.

The FDA "Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories" points out, that during FDA Inspections Re-Test Results should be assessed and verified with a special particularity. Especially the rationale for the re-testing should be challenged. Unfortunately, the FDA Guidance for Industry "Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production" rather addresses the handling of classical chemical analysis OOS and does not really provide help for the handling of microbial deviations.

Pre-Conference Workshop "Microbiological Deviations"

5 May 2015, Prague, Czech Republic

Background, cont'd

On the contrary to chemical/physical tests in quality control, microbial OOS results necessitate special questions and involve challenges like the constrained recovery, effects of stressed microorganisms, influence of the used nutrient media inhomogeneous distribution of the microorganisms and so on. Following, a comprehensive root cause analysis and risk assessment is extremely important, including the necessary documentation.
Furthermore, basic definitions are also important. What are "Out-of-Specification", what are "Out-of-Limit" and what are "Out-of-Expectation" results and what are the necessary approaches and strategies to handle such results according to regulatory requirements?

Target Audience

Employees and managers of microbiological Quality Control laboratories who are involved in

- Testing of microbiological quality
- Handling and risk assessment of microbiological deviations
- Root cause analysis
- Microbiological CAPA
- Communication and tracing of microbiological contract laboratories

Programme

Handling of OOL/OOS Results in Biopharmaceutical Manufacturing

- Limit Definitions
- Deviation Management
- Case-by-Case Assessment of Bioburden Excursions

DR SVEN M. DEUTSCHMANN, ROCHE

EM Deviation Strategy - Non Sterile Drug Product Manufacturing

- Clear differentiation between initial non-critical and critical deviations
- Established standard procedure
- Clear criteria for evaluation

DR ESTHER MARTY, NOVARTIS

OOS in Sterility Testing

- Regulatory Requirements
- Immediate Measures and Root Cause Analysis
- Deviation Report
- CAPA

DR FREIMUT WILBORN, BERLIN CHEMIE

Pharmaceutical Water Qualities – Handling of OOS/OOL Results

- Definition of OOS and OOL
- Regulatory requirements
- Assessment and root cause analysis
- Alert levels and trending

DR WOLFGANG EDER, ROCHE DIAGNOSTICS

Dealing with OOS results in endotoxin testing

- Definition of OOS and OOL
  - What is an OOS result
  - The previous "FDA Guideline" approach
  - Our current approach
- Roles and responsibilities
- Analytical and technical investigations
- Decision making process
- Retest/Re-analysis/Resampling
- Conclusions and remarks

DR GUY ROEHRIG, LILLY

OOS and objectionable microorganisms in non-sterile drug products

- Important points to consider when performing root cause investigations
- Objectionable microorganisms: risk assessment and origins of contamination
- Examples of real cases

DR DAVID ROESTI, NOVARTIS

European Microbiology Conference

6-7 May 2015, Prague, Czech Republic

Objectives

These two events offer you a unique possibility to become acquainted with ongoing regulatory requirements, the development of microbiological methods for quality and process control as well as with the recent experiences in microbial contamination control. Speakers from different scopes of pharmaceutical microbiology will give you the chance to get to know the different views on versatile microbiological topics. Also, as a participant you will have ample opportunity to discuss your specific issues with speakers and other participants

Background

The role of pharmaceutical microbiology is getting more and more important. It is also increasingly in the focus of regulators during product submission and inspections. With the harmonisation of the different pharmacopoeias the harmonised methods must be implemented. The challenge is therefore to satisfy regulatory requirements alongside management's financial expectations.
Furthermore, the field of Rapid Microbiological Methods has been developing very fast in the last years. It promises possibilities to optimise the factors time and money in microbiological in-process-control and release

Target Audience

This conference is of interest to professionals in microbiology from
- Pharmaceuticals and Biopharmaceutical Companies
- Academic Research Institutions
- Government Agencies
- Contract Service Laboratories

who are involved in
- Quality Affairs
- Research and Development
- Validation
- Regulatory Affairs
- Contamination Control
- Monitoring

Moderators

Sven M. Deutschmann, Barbara Gerten, Axel Schroeder

Programme

Key Note

Agency's current thinking on microbiology related topics
- Regulatory Developments/Microbiological Inspection Experiences/ Control Sterile Products

DR JESSICA COLE, FDA/CDER OFFICE OF PHARMACEUTICAL QUALITY, DIVISION OF MICROBIOLOGY ASSESSMENT

Module 1: Methods and Method Validation

BioTrak - Three Portable Instruments in One
- BioTrak Real-Time Data – Benefits
- RMM Challenges
- Real Case Studies: BioTrak Applications

ROCCO PETRIZZO, TSI

Validation of an Automated Rapid Bioburden Enumeration System for Pharmaceutical Water Testing
- Validating the Growth Direct System against common microorganism isolates found in pharmaceutical water systems
- Stressed organism validation method and results
- Time-to-Result determination
- LIMS integration with Growth Direct system for direct data entry

PAUL LUKES, GLAXOSMITHKLINE

A newly developed approach for the rapid detection and identification of adventitious viruses in biopharmaceuticals
- The background
- The idea/principle
- The assay performance

DR ANNETT KILIC, GBO

Programme, cont'd

Evaluation of classical and modern methods for bacterial identification: Comparison of VITEK®-2 compact (biochemical analysis) to VITEK®-MS (MALDI-TOF mass spectrometry) and MicroSeq® Microbial Identification System (16S-rDNA sequencing)

- Brief introduction of the various identification methods and their pros and cons
- Comparative identification of microorganisms from hygiene monitoring using biochemical as well as molecular methods
- Which method is most suitable for which purpose?

DR STEFANIE BAYER, L+S AG

New Bioindicators for H_2O_2 Sterilisation

- Highest quality indicators
- Homogenous spore layer
- Lot size (up to 50000 indicators)

DR ANNA SCHERZINGER, HYGLOS GMBH

Qualification/Validation of moist heat and dry heat sterilization processes: Microbiological Studies

- Design of microbiological studies within the Qualification/Validation of moist heat and dry heat sterilization processes
- Usage of bioindicators and endotoxin indicators
- Methods
- Case-studies and problems

ANJA FRIEDRICH, BSL

Module 2: Contamination Control and Disinfection

Validation of Disinfectants for use in Cleanrooms

- The process for evaluation of disinfectants to be used in cleanrooms
- Review of disinfectant testing methods and their suitability for evaluation of cleanroom disinfectants
- Points for consideration when defining the validation protocol

LAURA GUARDI, ECOLAB

New Studies – Light induced disinfection of garment and surfaces

- New innovative cleanroom textile with a light induced self-disinfection
- Mechanism and efficacy
- Conception of gowning areas for such new garment system

CARSTEN MOSCHNER, DASTEX

Solutions for overcoming testing challenges with disinfectant coupon studies

- Fungal and Bacterial spore case studies in cleanrooms will be covered.
- Advances in cleaning and disinfection methods will be covered.
- Industry regulations and warning letters will be covered related to disinfectant qualification and spore outbreaks.
- Common causes for coupon testing failures will be covered and solutions will be covered to overcome obstacles.

JIM POLARINE, STERIS

Holding Studies and Microbial Challenge Tests

- Review of some challenges in Antimicrobial Effectiveness Testing of preserved and non-preserved products
- Microbial growth promotion test and determination of growth rates for different test strains
- Microbial Challenge Test and Bioburden simulation
- Case studies and failure investigations

JÖRG DEGEN, BSL

Programme, cont'd

Module 3: Learning from cognate industries

Validation of Microbiological Systems in Manufacturing

- Modern Test Methods
- In Line Control
- Operating Procedures
- Sanitization
- Need for an industry wide approach

NEIL LEWIS, PROCTER & GAMBLE

Further Developments of ISO Methods Revision

- Validation of alternative methods in food and drinking water testing
- New and revised ISO methods in food and water testing

BARBARA GERTEN, MERCK

Speakers

Dr Stefanie Bayer, Department Head Molecular Biology, Labor L+S AG, Germany
Stefanie studied Biology with the focus on Microbiology and Biochemistry at the University of Würzburg. During her dissertation, she worked at the Institute of Microbiology at the University Hospital Erlangen. After two years working in a diagnostic laboratory, she joined 2012 Labor L+S AG. There she is as department head of molecular biology responsible for molecular biological analysis with the focus on microbiological identification.

Dr Jessica Cole, FDA/CDER Office of Pharmaceutical Quality, Division of Microbiology Assessment
Jessica Cole studied Microbiology at the University of Georgia and holds a Doctor of Philosophy (PhD), Emerging Infectious Diseases from Uniformed Services University of the Health Sciences. Since 2009 she is as Product Quality Microbiology Reviewer at the FDA.

Dr Jörg Degen, Head of Microbiology, BSL BIOSERVICE Scientific Laboratories GmbH
Jörg Degen studied Biology at the University of Würzburg. He obtained his PhD at the Fraunhofer Institute for Interfacial Engineering and Biotechnology (IGB)/ University of Stuttgart-Hohenheim. 2006 he joined BSL Bioservice and in his current position, he is the head of BSL's Microbiology Laboratory.

Dr Sven M. Deutschmann, Roche Diagnostics GmbH, Germany
Sven Deutschmann studied biology (major: microbiology, biochemistry and biotechnology) at the University of Braunschweig where he obtained his PhD in cell culture technology. In 1995 he joined Boehringer Mannheim GmbH, now Roche Diagnostics GmbH, as Manager QC. He was responsible for the micro- and cell biological analytics of QC and In-Process-Control-samples in the production of biotechnological derived active pharmaceutical ingredients and for the environmental monitoring program in the production areas. Since 2001 he is Director of the Microbiology QC Department. He is member of the Microbiology Commission and the Working Party "Pyrogentests" of the German Pharmacopoeia Commissions and specialist resp. member in the Working Parties "Monocyte Activation Test" and "Bacterial Endotoxins" of the European Pharmacopoeia Commissions.

Dr Wolfgang Eder, QC Environmental Monitoring, Roche Diagnostics, Germany
Wolfgang holds a PhD in microbiology at the University of Regensburg (Germany). After working at Diversa Corporation (USA), profos AG (Germany) and the University of Regensburg (Germany) he joined Roche in 2006. Currently he is Senior Manager Quality Control for Environmental Monitoring and Cleaning in the Pharma Division at Roche Diagnostics GmbH (Germany) and involved in several RMM projects.

Anja Friedrich, Biologist, BSL, Germany
Anja Friedrich studied biology at the TU Munich with focus on microbiology and molecular biology. In that time she worked as scientist at the Institute for Pharmacology und Toxicology at the TU. In 1994 she joined BSL Bioservice where she was involved in building up the microbiological division at BSL as deputy head. She is a member of the working group Cleaning, Disinfection and Sterilization of the ZLG. Since 2011 she is Senior Manager Marketing and Sales Microbiology.

Barbara Gerten, Merck Millipore, Darmstadt, Germany
After her studies in microbiology and biochemistry, Barbara Gerten was employed in different companies responsible for QC and R+D. Since 2008 she is working in Merck Millipore Biomonitoring R+D in different positions. She is a member in several national and international bodies of microbiological topics in ISO and CEN and a member of the Advisory Board of ECA RMM Interest Group.

Laura B. Guardi, Global Validation Manager, Ecolab Contamination Control, United Kingdom
Laura Guardi studied Microbiology at the University of Manchester.. After graduation she worked for at Eli Lilly, Unilever, Medimmune and Novartis Vaccines in positions of increasing responsibility in the areas of QC/QA/ Compliance. She joined Ecolab Contamination Control in 2012 and currently holds the position of Global Validation Manager.

Dr Annett Kilic, Key Account Manager, Biopharm. Applications / Div. Diagnostics, Greiner Bio- One, Germany
At Greiner Bio-One GmbH Dr Annett Kilic has been involved in the development of bacterial, viral and human identification systems used by the biopharmaceutical industry since 2012. Educated as a Cell and Molecular Biologist, she worked at the Department of Haematology and Oncology at the University Medical Centre in Freiburg, Germany. In 2006 she moved to the Centre of Molecular Biology of the University of Heidelberg (ZMBH) where she obtained her Ph.D. and also worked as a PostDoc.

Neil Lewis, Procter & Gamble, USA
Studied at the Univerity of Salfird and graduated in Microbiology and Parasitology 1979. Worked 12 years as site microbiologist for Max Factor and Revlon..1991 he joined P&G as Regional Quality Assurance Manager, Heath and Beauty Care and from 1996 – 1999 as Site QA Manager followed by the position as QA Manager HHC. Currently, as Global Technical Leader Microbiology Delivery, he is responsible for the microbiological performance of some 70 manufacturing sites globally and the development of new microbiological techniques for QC. He provides techncial and transformational leadership to the manufacturing micorbiology organizationa and the Quality Assurance organization.

Paul Lukes, Microbiologist, GlaxoSmithKline - GMS Rockville, USA
Paul Lukes is a QC Microbiologist at GlaxoSmithKline in Rockville, MD (site formerly Human Genome Sciences). Paul has worked in the Quality department supporting commercial and clinical biopharmaceutical manufacturing processes for the past 6 years. During his time in Biopharm, he was responsible for project execution and manufacturing support, specifically leading initiatives to implement new technologies to improve control of the manufacturing process and increase efficiency of QC testing. Paul holds a B.S. degree in Chemistry with a concentration in Biochemistry and is attending Johns Hopkins University as a 2015 candidate for a M.S degree in Bioinformatics.

Dr Esther Marty, Senior QA Specialist, Novartis Pharma Stein AG, Switzerland
Esther Marty studied Biology at the University at the University of Zürich and graduated in Food Biotechnology at the ETH Zürich. In 2012, she joined Novartis Pharma Stein as Coordinator of QC Lab (Microbiology, Non Sterile Drug Products). 2014 she became QA Specialist, Microbiology of Non-Sterile Drug Products

Carsten Moschner, CEO Dastex GmbH & Co. KG, Germany
Carsten Moschner studied engineering economics at the University for applied Sciences in Karlsruhe. Currently he is CEO of Dastex with a focus on research and development as well as optimising of textile cleanroom garment. Carsten is a member of several expert committees, e.g. deeply involved in the new VDI 2083 chapter about the suitability of cleanroom equipment

Rocco Petrizzo, M.Sc , Application Specialist Contamination Control, TSI GmbH
Rocco studied at the Universities of Modena, Catania and Barcelona. After is research between Cornell University and University of Barcelona, he joined 2007 GE Healthcare as Technical Support Specialist. Currently he is EMEA Contamination Control Application Specialist taking care of the Viable Counters business.

Jim Polarine Jr., MA., Formulated Chemistries Technical Service Manager, STERIS Corporation
Mr Polarine graduated from the University of Illinois with a Master of Arts in Biology. He has been with Steris for over 13 years and is today technical service manager. He is also currently active on the PDA task force on cleaning and disinfection and has co-authored the PDA technical report on cleaning and disinfection. He is part of the faculty at the University of Tennessee Parenteral Medication course.

Guy Roehrig, Lead Scientist, Microbiology Laboratory LILLY France S.A.S.
Guy Roehrig first joined Lilly over thirty years ago, and was in charge of animal testing. As soon as alternative methods to animal testing became available, he specialized in the Bacterial Endotoxin Test (BET) and worked with Regulatory Affairs on the replacement of the pyrogen test by the BET. Recognized as an expert in this field, Guy Roehrig was invited to join a working group on this subject by the SFSTP (Société Française des Sciences et Techniques Pharmaceutiques. He co-chaired an international PDA/SFSTP conference on Bacterial Endotoxins in Paris (2009) as well as presenting the draft of the SFSTP teamwork at the PDA annual conference in Orlando (2010), at the European PDA conference in Barcelona (2011) and in Tours at the A3P meeting in March 2012. Guy Roehrig has been responsible for introduction of cell culture based bioassays in Lilly laboratories, as well as being involved in the implementation of a new bacteriological identification system based on genotyping methods. After a 2 year break in order to complete a Master's degree in Translation Studies, he is now back at Lilly, looking into newer methods such as mass spectrophotometry for bacterial ID, automatisation of endotoxin tests or development of a new cell base bio-identity assay.

Dr David Roesti, Novartis Pharma Stein AG, Switzerland
David holds a PhD in microbial ecology from the University of Neuchâtel, Switzerland and has 14 years experience in the field of microbiology within various domains. Currently, David is leading the RMM team and the Novartis Pharma expert network in microbiology at Novartis Pharma AG in Stein Switzerland. Prior to this assignment, David was the laboratory supervisor for the microbiological testing of non-sterile drug products at Novartis Pharma Stein AG.

Dr Anna Scherzinger, Senior Scientist and Project Manager, Hyglos GmbH
Anna Scherzinger is Project Manager in Research and Development at Hyglos GmbH, Germany. Anna studied biology with main focus on microbiology and cell biology. She received her Diploma in Biology in 2006 and her Ph.D. in Biochemistry in 2011 from the University of Regensburg, Germany, the latter in cooperation with Hyglos GmbH. Her current research interests concentrate on Biological Indicators for H2O2 decontamination and Endotoxin detection as well as phage derived lytic enzymes for combating pathogen bacteria.

Dr Freimut Wilborn, Head QC Microbiology, Berlin Chemie AG, Germany
Freimut Wilborn studied Biology at the Johann Wolfgang Goethe-Universität Frankfurt am Main. After his graduation, he was Postdoc at the Medical Department for Haematology und Oncology of UKRV Rudolph Virchow. After positions in QC and QM at BioteCon and Arcensus, he joined 2013 Berlin Chemie AG.

Social Event
On 6 May you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.microbiology-conference.org
www.gmp-compliance.org

Dates
Workshop Microbiological Deviations
Tuesday, 05 May 2015, 09.00 - 17.00 h
(Registration and coffee 08.30 – 09.00 h)

European Microbiology Conference
Wednesday 06 May 2015, 09.00 – 17.30 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 07 May 2015, 08.30 – 16.30

Venue
Corinthia Hotel Prague
Kongresova 1
14069 Prague, Czech Republic
Phone +420 (261) 191 111
Fax +420 (261) 225 011

Fees (per delegate plus VAT)
Pre-Conference Workshop Microbiological Deviations
ECA Members € 790
APIC Members € 840
Non-ECA Members € 890
EU GMP Inspectorates € 445
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch, and all refreshments during the conference.
VAT is reclaimable.

European Microbiology Conference
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the 6 May, lunch on both days and all refreshments during the conferences. VAT is reclaimable

Pre-Conference Workshop combined with the European Microbiology Conference
ECA Members € 2,080
APIC Members € 2,180
Non-ECA Members € 2,280
EU GMP Inspectorates € 1,140
Save up to € 400
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the 6 May, lunch on all three days and all refreshments during the conferences. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Conference Language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.
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P.O. Box 10 17 64
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Mr Axel Schroeder (Operations Director) at +49-62 21/84 44 10 or per e-mail at schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Jessica Stürmer (Organisation Manager) at +49-62 21/84 44 43 or per e-mail at stuermer@concept-heidelberg.de.

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☐ **Workshop Microbiological Deviations**
5 May 2015, Prague, Czech Republic

☐ **European Microbiology Conference**
6-7 May 2015, Prague, Czech Republic

☐ **Workshop Microbiological Deviations AND European Microbiology Conference**
5-7 May 2015, Prague, Czech Republic

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